

## **Medical Device Regulatory Requirements for Saudi Arabia**

**Disclaimer:** The information contained on this website is derived from public sources and is current to the best of our knowledge. For detailed and definitive information about a country's laws and policies, the government of the country concerned should be consulted.

### **Introduction to the Saudi Arabia Regulatory System**

Ministry of Health (MOH) in Saudi Arabia is the government entity charged with meeting Saudi's health care needs and regulations. The Saudi Arabia medical market relies entirely on the imports of medical equipment, and U.S. manufacturers continue to enjoy a good market share. The potential for U.S. manufacturers to take part in the expansion of this sector will be enhanced with the enactment of a new foreign investment law. The law gives foreign companies the ability to own 100 percent of their investment, while enjoying the same investment incentives given to Saudi companies.

### **Medical Regulations**

Saudi Arabia does not have any official standards for medical products. Radiology equipment and body implants are exempted from custom duties. A seven percent tariff applies to magnetic resonance imaging (MRI) and ultrasound equipment entering Saudi Arabia. Also a 20 percent tariff is imposed on imported non-electric beds. All other medical equipment carries a 12 percent added value duty.

### **Licensing**

With the following exceptions, there are no licensing requirements for medical devices in Saudi Arabia:

Radio immunoassay equipment which requires a license from the Saudi Ministry of Interior prior to importing; and

Distillation equipment that requires a license from the Ministry of Health.

Imported medical equipment is not subject to local testing requirements above and beyond those of the U.S. FDA or European notified certified bodies. The Saudi government does not arbitrarily apply standards to imports. Internationally recognized standard, i.e. ISO 9000, is accepted. There are no

locally written technical standards that apply to medical equipment except the electrical standard, namely, 127 volts, 60 Hz. Some hospitals, however, will accept 220 volts, 60 Hz.

### **Labeling**

Medical equipment sold directly to the Saudi Ministry of Health (MOH) requires special labeling information, i.e., MOH logo consisting of two swords and a palm tree in the middle. Information on the labeling can be obtained directly from the Ministry of Health at:

Ministry of Health  
Medical Supply Department  
Old Airport Road  
Riyadh 11176, Saudi Arabia  
Phone: (966 1) 401-2220-5555 ext.1277 or 401-2392 ext. 1277  
Fax: (966 1) 402-6944 or 402-9876  
Contact: Dr. Saad bin Madi Al-Madi, Executive Director

The Saudi government does not require local importers to provide pricing information as a requirement to import, except for medicines and drugs. There is no reimbursement policy in Saudi Arabia.

Used or refurbished medical equipment is allowed entry into Saudi Arabia.

Having a Saudi agent is critical for sales in the public sector since most government tenders are only open to local suppliers and are heavily biased towards those companies with the strongest local representation. Likewise, a qualified, on-site Saudi representative is extremely important in gaining access to private Saudi end-users.

Key Contacts in Saudi Arabia:

Marilyn Taylor, Principal Commercial Service Officer

[Marilyn.taylor@mail.doc.gov](mailto:Marilyn.taylor@mail.doc.gov)

U.S. Commercial Service

P. O. Box 149

Jeddah 21411- Saudi Arabia

Tel: (966-2) 660-0009 Ext. 203

Fax: (966-2) 664-4148

Ministry of Interior Health Affairs  
P. O. Box 3643 Riyadh 11490  
Saudi Arabia  
Phone: (966 1) 477-1390  
Fax: (966 1) 478-8292

National Guard Health Affairs  
P. O. Box 22490 Riyadh 11490  
Saudi Arabia  
Phone: (966 1) 252-0088  
Fax: (966 1) 252-0050

Riyadh Al-Kharj Hospital Program  
P.O. Box 7897 Riyadh 11159  
Saudi Arabia  
Phone: (966 1) 477-7714  
Fax: (966 1) 476-9250

Executive Board of the Health Ministers' Council for the GCC States  
P.O. Box 7431 Riyadh 11462  
Saudi Arabia  
Phone: (966 1) 488-5270  
Fax: (966 1) 488-5266

Last updated on 3-8-06 by TH